

(PCT Article 36 and Rule 70)

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| Date of submission of the demand | Date of completion of this report |
| Name and mailing address of the IPEA/EP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/011797

Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-27 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-23 _____ received by this Authority on 29.08.2005 with letter of 29.08.2005
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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| Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | |
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| 1. Statement | | | |
| Novelty (N) | Claims | 1-23 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-23 | NO |
| Industrial applicability (IA) | Claims | 1-23 | YES |
| | Claims | | NO |
| 2. Citations and explanations (Rule 70.7) | | | |
| <p>1. Reference is made to the following documents:</p> <p>D1: US-A-4 512 969 (CHEN ET AL) 23 April 1985 (1985-04-23)</p> <p>D2: EP-A2-0 039 788 (BASF AKTIENGESELLSCHAFT) 18 November 1981 (1981-11-18)</p> <p>D3: WO 2004/000916 A2 (NANOPHASE TECHNOLOGIES CORPORATION) 31 December 2003 (2003-12-31)</p> <p>D4: EP-A2-0 750 899 (SHISEIDO COMPANY LIMITED) 2 January 1997 (1997-01-02)</p> <p>D5: EP-A2-0 446 636 (SHOWA DENKO KABUSHIKI KAISHA) 18 September 1991 (1991-09-18).</p> <p>2. The amendments submitted by the applicant (29 August 2005) satisfy the requirements of PCT Article 34(2)(b). The application now relates to formulations for active substances containing a fungicide and at least one statistical radical copolymer synthesised from monomers I (acrylic ester acid or acrylamide sulphonic acid) and II (derivative of acrylic acid, acrylic ester, or acrylamide), wherein the polymer must contain at least one (meth)acrylic acid ester of formula IIb in a polymerised form.</p> | | | |

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3.1 Novelty (PCT Article 33(2))

Prior to the examination in respect of novelty, it should be mentioned that the subject matter of claims 1, 2, 4 and 5 lacks clarity since claims 2, 4 and 5 appear to be inconsistent with claim 1. The reason therefor is that according to claim 1 monomer IIb is essential whereas in claims 2, 4 and 5, which are dependent on claim 1, this feature is considered to be only optional or is not even present. Since claim 1 is the independent claim and the applicant considered IIb to be an essential feature (see the letter of 29 August 2005, final paragraph), **the examination of the claims in respect of novelty has been based on independent claim 1.** The subject matter of claims 2, 4 and 5 is therefore considered to have been encompassed by claim 1.

D1 relates (see the abstract) to the production of dispersions of a hydrophobic active substance in an aqueous medium. The dispersed phase consists of particles of a synthetic polymer having a mean diameter of between 0.02 and 0.2 μm , said particles being loaded with the hydrophobic active substance. The active substances might be insecticides, herbicides, miticides, hormones, vitamins or enzymes. The monomers in the preferred copolymers (see columns 9-13) comprise at least alkyl acrylate and 3-acryloyloxypropan-1-
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sulphonic acid. Most of the preferred polymers, and in particular L1, L2, L4, L5, L8-L18, L20, L22-L30, L36, L37, L41-L43, L46-L54, L56, L59, L65, L68, L71, L72, L74 and L76, correspond to the polymers defined in claim 1. Methyl parathion and parathion, respectively, are dispersed in examples 1 and 2.

D2 discloses (see the abstract) the production of formulations of copper complexes for controlling crop pests. In example 20, a copper complex is stabilised in a solution, using a copolymer composed of 1/3 acrylic acid, 1/3 maleic anhydride and 1/3 acrylamidodimethylpropane sulphonic acid. The solution is stable in storage, is miscible with water in any ratio thereto, and leaves a water-resistant residue when dried.

D4 relates (see the abstract) to cosmetic emulsions or solutions which are stabilised from a copolymer of (meth)acrylamidoalkyl sulphonic acid and N-substituted (meth)acrylamide. Synthesis examples 1-12 disclose the production of the stabilising copolymers by means of which the compositions of examples 4-9 are stabilised.

Example 33 of **D5** discloses a pharmaceutical composition based on a copolymer of N-vinylacetamide, acrylic acid and 2-acrylamid-2-methylpropane sulphonic acid.

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Since the active substance formulations defined in **D1**, **D4** and **D5** do not contain fungicides and the polymers of **D2** do not include any monomers of formula IIb, **D1**, **D2**, **D4** and **D5** do not anticipate the subject matter of claim 1, nor are said documents relevant to the novelty of the further independent claims - or of claims 19-23, in which the active substance formulations of claim 1 are also implicit.

3.2 Inventive step (PCT Article 33(3))

D1 is considered to be the closest prior art. The subject matter of independent claims 1 and 19-23 differs from that of **D1** in that the formulated active substance is a fungicide. The problem addressed by the application can consequently be regarded as that of providing nanodispersions of fungicides that are highly soluble in an aqueous medium.

For a person skilled in the art, it is evident that active substances with similar properties with respect to water-solubility can be formulated in the same way regardless of the biological action thereof. For this reason, a person skilled in the art would formulate the fungicides according to the application using the polymers according to **D1** as fungicidal nanoparticulate dispersions, thus arriving without inventive input at active substance formulations such as those claimed.

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The dependent claims do not appear to contain any features which, combined with the features of any claim to which they refer, meet the PCT requirements for inventive step. It should be noted here that a number of dependent claims differ from **D1** by virtue of the composition of the polymer. The problem addressed in these claims would be that of producing alternative nanoparticulate active substance combinations. However, it is not clear whether the problem addressed therein can be solved for the whole of the claimed scope of protection. The fact that claim 23 relates only to selected combinations of active substances, for which a specific mean particle diameter of less than 1 micrometer is claimed, leads to uncertainty as to whether all the claimed active substance formulations yield the desired nanodispersions. In consequence, no inventive step can be acknowledged.

The applicant is further advised that, similarly, no inventive step can be acknowledged for claims containing definitions of aryl groups in which the aryl group can be substituted but the potential substituents are not given, since a definition of this kind encompasses formulations that are not as close to the given examples as the formulations described in the prior art.

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3.3 Industrial applicability (PCT Article 33(4))

Claims 1-23 are considered to be industrially
applicable.

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Box No. VI

Certain documents cited

1. Certain published documents (Rule 70.10)

Application No.
Patent No.Publication date
(day/month/year)Filing date
(day/month/year)Priority date (valid claim)
(day/month/year)**See Supplemental Box.**

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

5. Contrary to PCT Rule 5.1(a)(ii), the description does not cite documents **D1** and **D3** or indicate the relevant prior art disclosed therein.

Box No. VIII **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

- 6.** The subject matter of claims 1, 2, 4 and 5 lacks clarity (PCT Article 6). Claims 2, 4 and 5 appear to be inconsistent with claim 1 since monomer IIb is an essential feature with regard to claim 1 whereas with regard to claims 2, 4 and 5, which are dependent on claim 1, said feature is considered to be only optional or is not even present.

The preferred embodiments of claim 23 fail to satisfy the requirements of PCT Article 6 (see also the PCT Guidelines, paragraph 5.40).

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box VI**

- 4.** D3 was published after the priority date (30 October 2003) claimed by the present application, namely on 31 December 2003 with a priority date of 4 February 2002. If the priority claimed by the present application is legitimate, **D3** does not belong to the prior art (PCT Rule 64.1 (b)).